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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AEDER, SEAN E	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,031	GUELLY ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-65 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 19, 22, 27, 31-33, and 60 as specifically drawn to the "special technical feature" of an isolated polypeptide, a pharmaceutical composition comprising said polypeptide, and a method of treating a patient comprising administering said polypeptide.
(Upon election of group I, Applicant must select a single SEQ ID NO from claims 1, 19, 22, 27, 33, or 60, as each sequence represents a separate special technical feature and not a species.)

Group II, claim(s) 3-7, 13-16, and 19-23, as specifically drawn to the "special technical feature" of a polynucleotide and a pharmaceutical composition comprising said polynucleotide.
(Upon election of group II, Applicant must select a single SEQ ID NO from claims 1, 5, 6, 19, or 22, as each sequence represents a separate special technical feature and not a species.)

Group III, claim(s) 8-11, 17-18, and 22, as specifically drawn to the "special technical feature" of a cell and a pharmaceutical composition comprising said cell.
(Upon election of group III, Applicant must select a single SEQ ID NO from claims 5 or 22, as each sequence represents a separate special technical feature and not a species.)

Group IV, claim(s) 12, 19 and 22, as specifically drawn to the "special technical feature" of an antibody and a pharmaceutical composition comprising said antibody.
(Upon election of group IV, Applicant must select a single SEQ ID NO from claims 1, 19, or 22, as each sequence represents a separate special technical feature and not a species. Applicant must also select whether the antibody is directed against a polypeptide or against a nucleic acid (see claim 12).)

Group V, claim(s) 24-26 and 34-46, as specifically drawn to the "special technical feature" of a method of determining differential expression of a polynucleotide or diagnosis wherein a polynucleotide is identified.
(Upon election of group V, Applicant must select a single SEQ ID NO from claims 24, 34, or 35, as each sequence represents a separate special technical feature and not a species.)

Group VI, claim(s) 24-26 and 47-59, as specifically drawn to the "special technical feature" of a method of determining differential expression of a polypeptide or diagnosis wherein a polypeptide is identified.
(Upon election of group VI, Applicant must select a single SEQ ID NO from claims 24, 47, or 48, as each sequence represents a separate special technical feature and not a species.)

Group VII, claim(s) 24-26, as specifically drawn to the "special technical feature" of a method of diagnosis wherein an antibody is identified.
(Upon election of group VII, Applicant must select a single SEQ ID NO from claim 24, as each sequence represents a separate special technical feature and not a species.)

Group VIII, claim(s) 27-33 and 60, as specifically drawn to the "special technical feature" of a method of treating a patient comprising administering a polynucleotide.
(Upon election of group VIII, Applicant must select a single SEQ ID NO from claims 27, 33, and 60, as each sequence represents a separate special technical feature and not a species.)

Group IX, claim(s) 27, 31-33, and 60, as specifically drawn to the "special technical feature" of a method of treating a patient comprising administering a cell.
(Upon election of group IX, Applicant must select a single SEQ ID NO from claims 27, 33, and 60, as each sequence represents a separate special technical feature and not a species.)

Group X, claim(s) 27, 31-32, as specifically drawn to the "special technical feature" of a method of treating a patient comprising administering an antibody.
(Upon election of group X, Applicant must select a single SEQ ID NO from claim 27, as each sequence represents a separate special technical feature and not a species.)

Group XI, claim(s) 61-65, drawn to the "special technical feature" of a method of identifying a pharmacologically active compound.
(Upon election of group XI, Applicant must select a single SEQ ID NO from claim 61, as each sequence represents a separate special technical feature and not a species.)

The inventions listed as groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: groups I-XI encompass different special technical features as identified in the groupings above. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different *categories* of inventions unity of invention will only be found to exist if specific combinations of inventions are present.

The allowed combinations do not include multiple products and multiple method of using said products, as claimed in the instant application. Hence, only one product and one process of use of said product relate to a single general inventive concept. The instant groups attempt to link products with the special technical feature of using said products in various methods. However, the products themselves do not share significant structural elements to the extent that each member could be substituted, one for the other, with the expectation that the same intended results would be achieved. For example, the polynucleotide sequences comprise significant differences in chemical compositions and lengths which, in turn, encode a multitude of amino acids with different chemical compositions and lengths, all of which would have different molecular weights, specificities, and biological activities. Since multiple products and multiple methods with different special technical features are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, se PCT article 7(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d). Accordingly, groups I-XI are not so linked to form a single inventive concept and restriction is proper.

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

> Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**
>
> Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 6, 9, 15, 16, 22, 33, and 60 are generic to a plurality of disclosed patentably distinct species of "**vectors**" comprising the following: a knock-out gene construct, a plasmid, a shuttle vector, a phagemid, a cosmid, a viral vector, and an expression vector (see claims 7 and 16). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on

the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 24-27, 31, 32, 35, 43, 48, and 56-60 are generic to a plurality of disclosed patentably distinct species of "**ailments**" comprising the following: cirrhosis, alcoholic liver disease, chronic hepatitis, Wilson's Disease, heamochromatosis, hepatocellular carcinoma, benign liver neoplasms, focal nodular hyperplasia, adenocarcinoma of the lung, adenocarcinoma of the stomach, adenocarcinoma of the kidney, adenocarcinoma of the colon, adenocarcinoma of the prostate, adenocarcinoma of the skin, adenocarcinoma of the breast (see claims 25, 26, 31, 32, 45, 46, 58, and 59). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct cell types with different morphologies and functions such that one species could not be interchanged with the other. Further, the above species are distinct ailments which differ at least in etiology, pathology, and mechanisms. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 34, 35, 47, are 48 are generic to a plurality of disclosed patentably distinct species of "**methods of detecting**" comprising the following: PCR, hybridization, gel electrophoresis, chromatographic techniques, immunoblot analysis, immunohistochemistry, enzyme based immunoassay, surface plasmon resonance, HPLC, mass spectroscopy, immunohistochemistry, and enzyme based immunoassay (see claims 37 and 50). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 34, 35, 38, 47, 48, and 51 are generic to a plurality of disclosed patentably distinct species of "**methods of comparing**" comprising the following: solid-phase based screening methods, hybridization, subtractive hybridization, differential display, RNase protection, two dimensional gel electrophoresis, chromatographic separation

techniques, immunoblot analysis, surface plasmon resonance, immunohistochemistry, and enzyme based immunoassay (see claims 38 and 50). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 24, 34, 35, 39, 47, 48, and 52 are generic to a plurality of disclosed patentably distinct species of "**samples from a patient**" comprising the following: liver tissue, liver cell, tissue from another specific organ subject to cancerous transformation, cells from another specific organ subject to cancerous transformation, blood, serum, plasma, ascetic fluid, pleural effusion, cerebral spinal fluid, saliva, urine, semen, and feces (see claim 39). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct cells, tissues, fluids, and other products found in or

produced by the human body, with different functions such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 24, 34, 35, 40, 41, 43, 47, 48, 53, 54, and 56 are generic to a plurality of disclosed patentably distinct species of "**reference samples**" comprising the following: liver cell, blood, serum, plasma, ascetic fluid, pleural effusion, cerebral spinal fluid, saliva, urine, semen, and feces (see claims 41 and 54). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct cells, tissues, fluids, and other products found in or produced by the human body, with different functions such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claim 61 is generic to a plurality of disclosed patentably distinct species of "**interaction assays**" comprising the following: enzyme cellular based reporter methods, fluorescence cellular based reporter methods, surface plasmon resonance, HPL, and mass spectroscopy (see claims 63-64). The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER